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AUG 24 1999

Waddell A. Biggart
Sughrue, Mion, Zinn, Macpeak & Seas, PLLC
Suite 800
2100 Pennsylvania Ave., NW
Washington DC 20037

In Re: Patent Term Extension
Application for
U.S. Patent No. 4,868,216

NOTICE OF FINAL DETERMINATION and REQUIREMENT FOR ELECTION

A determination has been made that U.S. Patent No. 4,868,216, which claims the human drug product FLOWMAX™ (tamsulosin hydrochloride), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 1,567 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent and/or a response to the requirement for an election may be made if filed within may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration and election, the Commissioner will issue a certificate of extension, under seal, for U.S. Patent No. 4,703,063.

The period of extension has been calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of July 10, 1998 (63 Fed. Reg. 37399). Under 35 U.S.C. § 156(c):

Period of Extension = ½ (Testing Phase) + Approval Phase
= ½ (3,163 - 762) + 366
= 1,567 days

Since the regulatory review period began August 19, 1987, before the patent issued (September 19, 1989), only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). (From August 19, 1987 to September 19, 1989 is 762 days; this period is subtracted from the number of days occurring in the testing phase according to the FDA determination of the length of the regulatory review period.) No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

The limitations of 35 U.S.C. § 156(g)(6) and 35 U.S.C. § 156(c)(3) do not operate to further reduce the period of extension determined above.

It is noted that applicant has also filed an application for patent term extension of U.S. Patent No. 4,703,063 based upon the regulatory review of the product FLOWMAX™. No more than one

patent may be extended based upon a regulatory review period of a product. 35 U.S.C. § 156(c)(4). When applications are filed for extension of the terms of different patents based upon the same regulatory review period for a product, the certificate of extension is issued to the patent having the earliest date of issuance unless applicant elects a different patent. Applicant is hereby **REQUIRED TO ELECT** a single patent for extension. In the absence of an election by applicant within ONE MONTH of the date of this notice, and in accordance with 37 CFR 1.785(b), the application for patent term extension in in the above-identified will NOT be granted.

If applicant elects the above-identified patent, upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.	:	4,868,216
Granted	:	September 19, 1989
Original Expiration Date	:	September 19, 2006
Applicant	:	Kazuo Imai, et al.
Owner of Record	:	Yamanouchi Pharmaceutical Co., Ltd.
Title	:	Sulfamoyl-Substituted Phenethylamine Derivatives and Process of Producing Them
Classification	:	514/603
Product Trade Name	:	FLOWMAX™ (tamsulosin hydrochloride)
Term Extended	:	1,567 days
Expiration Date of Extension	:	January 3, 2011

Any correspondence from applicant with respect to this matter should be addressed as follows:

By mail: Assistant Commissioner for Patents
Box Patent Ext.
Washington, D.C. 20231

By FAX: (703) 308-6916
Attn: Special Program Law Office

By hand: Crystal Plaza Four, Suite 3C23
2201 South Clark Place
Arlington, VA 22202

Telephone inquiries related to this determination should be directed to the undersigned at (703) 306-3159.

Karin L. Tyson
Senior Legal Advisor
Special Program Law Office
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

cc: David T. Read
Acting Director Regulatory Policy Staff, CDER
Food and Drug Administration
1451 Rockville Pike, HFD-7
Rockville, MD 20852

RE: FLOWMAX™
(tamsulosin hydrochloride)
FDA Docket No.: 97E-0359